REMARKS

The non-final Office Action of August 22, 2002 identifies claims 34, 41, 54-57 as 60-62 as pending in the present application with all of the claims to the non-elected invention being withdrawn. After further review, it is respectfully submitted that claim 35 should be included within the claims of the present application because it merely lists a preferred weight range for the hydrocolloid setting system identified in claim 34. In particular, generic claim 34 identifies the amount of the hydrocolloid setting system as 0.01 to 10% by weight while claim 36 narrows the weight range to 0.05 to 5% by weight. Quite clearly, the inclusion of claim 36 for examination herein does not raise any new issues nor does it require an expanded search.

Claim 34 has been amended to indicate that the hydrocolloid setting system provides a gelatin composition with gelling properties making the gelatin composition comparable to those which contain non-fish gelatins such as mammalian gelatins. The resulting gelatin composition may therefore be used to make hard gelatin capsules. Support for this language can be found in the specification at page 3, lines 15-23. As will become apparent from the discussion below, the cited prior art does not teach a gelatin composition having the particular components and properties required in claim 34 and the remaining pending claims of the application.

Claims 34, 41 and 54-57 stand rejected as obvious over Hansen et al. (U.S. Patent No. 6,423,346).

The Office Action states that the reference teaches a fish gelatin composition containing at least 50% by weight of fish gelatin, 0-10% of water and a hydrocolloid system comprising various polysaccharides such as gum Arabic. The Office Action acknowledges that the reference does not explicitly teach the specifically claimed amount of the hydrocolloids. However, the Office Action concludes that it would have been obvious to one of ordinary skill in the art to select a suitable amount of hydrocolloid because the expected result would be a fish gelatin composition with a hydrocolloid functioning as a protective agent. The rejection is hereby traversed and reconsideration is respectfully requested.

The present gelatin composition addresses the problem of trying to substitute fish gelatin for conventional mammalian gelatins to produce a gelatin composition having properties similar to the more conventional gelatin compositions.

Conventional gelatin compositions have been traditionally used for forming hard gelatin capsules. Gelatins from pig and bovine origin are preferably used for their gelling, film forming and surface-active properties. These properties are such that conventional gelatin compositions can be used to make hard gelatin capsules by dip molding as discussed in the present application on page 1, lines 13-26.

Fish collagen is another source of gelatin and in some cases may be a desirable substitute for the more conventional mammalian gelatins. However, fish gelatin lacks the gelling and setting abilities of mammalian gelatins and therefore lacks the ability to form various products such as hard gelatin capsules via the dip

molding process. As indicated beginning at page 2, line 1 of the present application, fish gelatin applications have been limited to products where a high viscosity of the solution without gel formation is desired such as, for example, in glue or food manufacturing or for microencapsulation of an active agent as referred to on page 2, line 5 of the present application.

However, prior to the present application, there was no effective means of forming a gelatin composition including fish gelatin which could be used for a variety of purposes including the formation of hard gelatin capsules. Applicants have discovered that by incorporating the respective amounts of fish gelatin and water as required in the present claims as well as a defined amount of a hydrocolloid setting system, one could obtain a gelatin composition containing fish gelatin having gelling properties which are similar to non-fish gelatin containing gelatin compositions so that the present gelatin composition could be used to form hard gelatin capsules.

Hansen et al. is directed to a particulate composition (column 2, lines 41-48). The particulate composition is typically in the form of microcapsules (column 4, lines 62-67) and therefore is similar to the microencapsulation products referred to in the present specification at page 2, line 5.

Microencapsulation products are particularly suited for making tablets as specifically described in Hansen et al. and in all of the examples provided therein. To the contrary, the present invention provides a gelatin composition comprising a unique combination of ingredients in specified amounts which enables the

composition to be used to form hard gelatin capsules through a dip molding process which is conducted by dipping mold pins into a hot solution of gelatin, removing the pins from the gelatin solution, allowing the gelatin solution attached on the pins to set by cooling and then drying and stripping the resulting shells from the pins. At no point in this process is there the formation or use of particulates or microcapsules as clearly taught by Hansen et al.

Column 3, beginning at line 43 of Hansen et al. discloses that the fish gelatin composition may comprise a variety of additional materials including hydrocolloids. As correctly noted in the Office Action, there is no teaching or suggestion of the amount of the hydrocolloids. Furthermore, there is no teaching or suggestion of forming any type of composition other than a microcapsule composition as set forth in all of the examples. Indeed, all of the examples fail to mention the use of a hydrocolloid in the preparation of the microcapsules.

Accordingly, one of ordinary skill in the art would not be led to the claimed invention by Hansen et al. because there is no teaching or suggestion of how to make a fish gelatin composition which is suitable for making hard gelatin capsules and which has gelling properties similar to gelatin compositions which do not contain fish gelatin. Furthermore, one of ordinary skill in the art is not provided any guidance on how to select a suitable hydrocolloid to form a setting system required in the present claims with an amount of the hydrocolloid suitable for forming the composition of the present invention. Again, none of the examples employ a hydrocolloid nor teach how it can be used to form a gelatin composition which meets

the requirements of the present invention. Thus, one of ordinary skill in the art is left to his or her own devices requiring much more than routine experimentation to arrive at the presently claimed invention.

Still further, it can not reasonably be argued that the reference composition inherently produces a fish gelatin composition meeting the requirements of the present claims. This is because there is no teaching or suggestion in the reference of producing anything but particulate compositions which is far afield from the invention claimed herein. In this regard, the Examiner's attention is directed to Example 1 of the present application appearing on page 7. It will be noted that as a first step in preparing the gelatin composition the hydrocolloid (kappa-carrageenan) and water are combined with potassium acetate to form a solution. The fish gelatin is then added to the solution and stirred until completely dissolved. The resulting fish gelatin solution can then be poured into a dipping dish of a pilot machine of conventional hard gelatin capsule production equipment. This is not possible with the particulate composition formed in accordance with the Hansen et al. reference.

It should be further noted that Hansen does not even require the presence of the water (0-10% by weight). This is further evidence that the entire thrust of Hansen et al. is to produce particulate compositions particularly in the form of microcapsules.

It is therefore submitted that the present claims patentably distinguish over Hansen et al. and withdrawal of the rejection of the 35 U.S.C. Section 103 is deemed proper and is respectfully requested.

Claims 60-62 stand rejected as obvious over Jones (U.S. Patent No. 4,892,766). Jones is stated to teach 2-piece hard gelatin capsule manufacturing wherein the capsules can be made by dipping mold pins into a hot solution of gelatin. The Office Action concludes that it would have been obvious to one of ordinary skill in the art to formulate such capsules by dipping a capsule into the forming mold with an aqueous gelatin solution. The rejection is hereby traversed and reconsideration is respectfully requested.

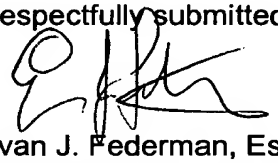
At the outset, Jones does not mention fish gelatin anywhere in the text of the patent. Jones is directed to a conventional hard gelatin capsule manufacturing process. However, Jones does not recognize the problems of using fish gelatin to achieve such hard gelatin capsules nor does Jones provide a solution to the problem. One of ordinary skill in the art reviewing the Jones' reference would desirably form a gelatin solution and could readily do so using conventional gelatins (i.e. mammalian gelatins). However, as taught in the present application, if fish gelatin were chosen (and there is no teaching or suggestion of using fish gelatin) one of ordinary skill in the art would find, in the absence of the present invention, that the gelling and film forming properties of such a composition were not suitable for forming hard gelatin capsules. This is the advance taught by the present invention.

It is therefore submitted that claims 60-62 are patentable over Jones et al. and reconsideration of the rejection set forth in the Office Action is deemed proper and is respectfully requested.

In view of the foregoing, Applicants submit that the present application is in condition for allowance and early passage to issue is therefore deemed proper and is respectfully requested.

It is believed that no fee is due in connection with this Amendment. However, if any fee is due, it should be charged to Deposit Account No. 23-0458.

Respectfully submitted,



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